REMARKS

Formal Matters

Claims 1-23, 30-34, 42 and 43 are pending after entry of the amendments set forth herein.

Claims 24-29 and 25-41 have been canceled above, without prejudice to the possibility of filing one or more continuing applications directed to the subject matter recited therein.

Claims 1-23 and 30-34 were examined. Claims 1-23 and 30-34 were rejected.

Applicant respectfully requests reconsideration of the application in view of the amendments and remarks made herein.

No new matter has been added.

The Telephone Interview

Applicant wishes to extend his appreciation to the Examiner for the courtesy provided to Applicants' representative during the telephone interview of June 1, 2007. During the interview, the Examiner indicated that he would reserve judgment until reading and considering further remarks made in this Office Action with regard to the grounds of rejection under 35 U.S.C. Sections 112, first paragraph, and 103(a).

This account is believed to be a complete and accurate summary of the interview as required by 37 C.F.R. § 1.133. If the Examiner believes that this summary is inaccurate or incomplete, Applicant respectfully requests that the Examiner point out any deficiencies in his next communication so that Applicant can amend or supplement the interview summary.

The Office Action

In the Official Action of April 17, 2007, the Examiner required cancellation of nonelected claims 24-29 and 35-41. In response thereto, Applicants have canceled claims 24-29 and 35-41 above, without prejudice to the possibility of filing one or more continuing applications directed to the subject matter recited therein.

Claims Rejected Under 35 U.S.C. Section 112, First Paragraph

Claims 1-23 and 30-34 were rejected under 35 U.S.C. Section 112, first paragraph as failing to comply with the written description requirement. The Examiner asserted that one of skill in the art cannot envision the detailed sequences of differential expression levels for the genus of disease processes. The Examiner further asserted: "The specification does not disclose a representative number of species of differential expression levels of disease[d] processes such that one of skill in the art would envision that applicant had possession of the full scope of the claimed invention. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method of isolating it."

In response thereto, Applicant is not clear about what the Examiner has referred to as "it" when requiring "more than a mere statement that it is a part of the invention and reference to a potential method of isolating it." Applicant notes that the present invention is not directed to or claiming a method of isolating or identifying detailed sequences of differential expression levels for the genus of disease processes, or for any disease process, but rather to compare effects of different treatments on expression levels and correlate these to phenotypic responses across a plurality of diseased tissues that include the genes from which the expression levels are measured. To further clarify this, Applicants have amended independent claims 1, 21 and 30 to recite that the differential expression levels used are from predetermined genes of diseased tissue samples. For example, paragraph [0062] on page 23 of the specification notes that differential expression readings of diseased tissues versus a reference, which may be supplied from an already existing source.

Further, it is respectively submitted that Applicant is not claiming detailed sequences of differential expression levels for the genus of disease processes. Rather, Applicant is claiming a method of screening treatments to identify those treatments that may cooperate beneficially to treat a disease. Applicant is not claiming any particular sequence of differential expression levels, but rather a technique for identifying potentially useful treatments. Since Applicant is not claiming even one sequence of differential expression levels, it is respectfully submitted that it follows that Applicant cannot be properly considered to be claiming the genus of sequences of differential expression readings of diseased tissues, and that the current ground of rejection as lacking an adequate written description is inappropriate.

The Examiner referred to Paik, Molecular Profiling of Breast Cancer, Curr Opin Obstet Gynecol 18:59-63 (2006), interpreting this document to show that the correlation of expression of multiple genes

in combination on a microarray is not predictable. However, on page 61, column 2, last 7 lines, Paik notes that 16 cancer genes were selected from an examination of 250 genes by individual QRT-PCR and were normalized with five reference genes. A mathematical algorithm, called the Recurrence Score, was developed based on expression levels of the 16 genes and used to evaluate patients. It is respectfully submitted that this indicates predictability of the use of those 16 genes as an evaluation tool.

Further in support of this position, Applicant is submitting herewith an abstract from a scientific journal article by Levy, entitled "Microarray analysis in drug discovery: an uplifting view of depression", SCI STKE, 2003 Oct 28; 2003(206):pe46, that discloses: "Not only is microarray analysis a valuable tool for drug evaluation and leading candidate development, but the genes identified as markers for the various drug classifications point to new directions for research into the underlying pathways responsible for human diseases, such as depression and psychosis." It is respectfully submitted that this is evidence that there are currently known genes, the expression levels of which have been used in drug discovery.

Further, Applicant is submitting herewith an abstract from a scientific journal article by Debouck et al., entitled "DNA microarrays in drug discovery and development", Nat. Genet. 1999 Jan; 21 (1 Suppl):48-50, that indicates: "DNA microarrays can be used to measure the expression patterns of thousands of genes in parallel, generating clues to gene function that can help to identify appropriate targets for therapeutic intervention. They can also be used to monitor changes in gene expression in response to drug treatments."

Still further, Applicant is submitting herewith a scientific journal article by Lombardi, entitled "Industrializing microarrays: High-throughput microarray analysis can help improve drug discovery and development", Modern Drug Discovery, December, 2004, American Chemical Society. On page 47, column 1 of the article, it discloses "Microarray technology has already revolutionized significant parts of the drug discovery process, but with the development of HT arrays, pharmaceutical companies can now more wholly implement and apply the technology. For example, at the beginning of the process, HT technology can play a role in disease pathway identification and validation, and later on, once a target has been identified, in compound screening and lead optimization."

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1-23 and 30-34 under 35 U.S.C. Section 112, first paragraph, as being inappropriate.

Claims Rejected Under 35 U.S.C. Section 112, Second Paragraph

Claims 1-20 were rejected under 35 U.S.C. Section 112, second paragraph as being indefinite. The Examiner indicated that claim 1 is vague and indefinite because it is unclear whether the preamble, as written indicates whether it is the "combination of treatments" or the "disease process" that impacts gene expression. In response thereto, Applicant notes that the preamble recites that it is the "disease process" that impacts gene expression, which is why the phrase "that impacts gene expression" follows the phrase "disease process" and not the phrase "combination of treatments". Applicant believes therefore, that the preamble is clear and definite as written. However, in view of the Examiner's suggestion made in the Advisory Action dated July 12, 2007, Applicant has amended claim 1 to change "that impacts" to –wherein the disease process impacts--.

In view of the above amendments and remarks, the Examiner is respectfully requested to reconsider and withdraw the rejection of claims 1-20 under 35 U.S.C. Section 112, second paragraph as being indefinite, as being inappropriate.

Claims Rejected Under 35 U.S.C. Section 103(a) (Muraca in view of Glinskii)

Claims 1-4, 6-22 and 30-33 were rejected under 35 U.S.C. Section 103(a) as being unpatentable over Muraca, U.S. Publication No. 2003/0049701 in view of Glinskii, U.S. Publication No. 2004/0053317. The Examiner maintained this ground of rejection for the same reasons provided in the previous Office Action.

In responding to Applicant's arguments, the Examiner asserted that Muraca compares the phenotypic response signature of diseased tissues with signatures of differential expression levels of diseased tissues when untreated. The Examiner referred to paragraph [0023] of Muraca as support for his assertion. Applicant respectfully submits that paragraph [0023] of Muraca describes placing a plurality of tissues and/or samples at different, known positions on the substrate of a microarray. By dividing the samples into different groupings, the microarrays enable ultra-high-throughput molecular profiling. Applicant was unable to locate any description or suggestion in paragraph [0023] of generating a phenotypic signature as claimed.

In contrast, the present invention discloses generating a single phenotypic signature that includes the treatment response values of the plurality of diseased tissues. This signature, generated as a vector, is then compared to the phenotypic/genotypic signatures of the features. A phenotypic/genotypic

signature is generated by making a vector of the expression values for that feature (and the same respective feature on the other microarrays for the other diseased tissues) across all microarrays for the plurality of diseased tissues. It is respectfully submitted that neither Muraca nor Glinskii discloses or suggests generating either a phenotypic response signature or a phenotypic/genotypic signature as claimed.

The Examiner's comments about Applicant's characterization of the terms "a", "and" and "the" in the specification are not understood. Muraca does not disclose generating a differential expression level signature representing the differential expression levels for each diseased tissue sample. Nor does Muraca disclose generating a phenotypic signature representing treatment response values of each of the diseased tissue samples. It follows that Muraca does not disclose comparing these signatures, since Muraca does not disclose generating either type of signature.

New Claims

Independent claims 42 and 43 have been presented above. Claim 42 combines the recitations of claims 1 and 5 and further recites that the claimed signatures are provided as vectors. Claim 43 combines the recitations of claims 21 and 23 and further recites that the claimed signatures are provided as vectors. It is respectfully submitted that claims 42 and 43 are allowable over the art of record, and an indication to such effect is respectfully requested in the next Official Action.

Conclusion

Applicant submits that all of the claims are in condition for allowance, which action is requested. If the Examiner finds that a telephone conference would expedite the prosecution of this application, please telephone the undersigned at the number provided.

The Commissioner is hereby authorized to charge any underpayment of fees associated with this communication, including any necessary fees for extensions of time, or credit any overpayment to Deposit Account No. 50-1078, order number 10030208-1.

Respectfully submitted,

Date: 8/7/07

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